IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

CARLOS PÉREZ-COTAPOS UGARTE, MARIA ISABEL URETA BAZÁN, CARLOS PÉREZ-COTAPOS SUBERCASEAUX, INVERSIONES ANE MIREN LIMITADA, SHERYL GROVE, and HOORIEH ALAGHEMAND, Individually and On Behalf of All Others Similarly Situated,

Plaintiffs,

v.

CASSAVA SCIENCES, INC., RICHARD JON BARRY, JAMES W. KUPIEC, REMI BARBIER, LINDSAY BURNS, and ERIC SCHOEN,

Defendants.

Case No. 1:24-CV-01525-DAE

DEFENDANTS CASSAVA SCIENCES INC.'S, RICHARD JON BARRY'S, JAMES W. KUPIEC'S, AND ERIC SCHOEN'S MOTION TO DISMISS PLAINTIFFS' AMENDED COMPLAINT

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Cases

This action is the latest in a string of overlapping securities class actions filed against these Defendants. All the others have been consolidated. Plaintiffs' Amended Complaint, Dkt. 49 ("Am. Compl."), is the third attempt by their counsel to take the mantle of lead counsel for this case and once again piggybacks on claims that have been pending and actively litigated for years in *In re Cassava Sciences, Inc. Securities Litigation*, No. 1:21-cv-751-DAE (the "Consolidated Action").[1]

The Amended Complaint reprises the same alleged scheme against the same Defendants and turns on the same core questions: the integrity of pre-clinical and clinical data concerning Cassava's Alzheimer's drug candidate, simufilam; the purported misconduct of Cassava's collaborator, Dr. Hoau-Yan Wang; an alleged effort by Defendants to cover up those issues following public criticism; and the supposed import of the same 2024 "corrective disclosures." The Amended Complaint's only claimed distinction is temporal. It begins the proposed class period one day after the Consolidated Action's class period ends, then points to a handful of subsequent statements—about investigations, Phase 2 data, and executive departures—as purported efforts to continue to perpetuate the same alleged deception.

Counsel's attempt to manufacture a distinct case to justify lead counsel status is flawed. To the extent it purports to offer anything new, the pleading fails to state a claim. It does not allege particularized facts showing that any challenged statement made during the alleged class period was false when made, that any Defendant acted with scienter, or that any purported corrective disclosure caused investors' losses. To the contrary, the targeted statements were accurate, and none of Plaintiffs' alleged "corrective" disclosures demonstrate otherwise.

[1] Defendants have filed Motions to Consolidate this action into the Consolidated Action, which, if granted, could obviate the need to decide this Motion to Dismiss. *See* Dkt. 53; Consolidated Action, Dkt. 338.

The Amended Complaint should be dismissed with prejudice if it is not consolidated into the existing Consolidated Action.

BACKGROUND

A. Factual Allegations in the Amended Complaint[2]

Cassava Sciences, Inc. ("Cassava") is a biotechnology company based in Austin. During the Proposed Class Period (October 13, 2023, through March 25, 2025), Cassava's only therapeutic candidate was simufilam, an investigational treatment for Alzheimer's disease. Am. Compl. ¶¶ 1–2. Between 2012 and 2021, Cassava completed pre-clinical research, a Phase 1 study, and two Phase 2 clinical studies of simufilam with the help of outside collaborator Dr. Hoau-Yan Wang of the City University of New York ("CUNY"). *See id.* ¶¶ 3–6. Cassava also began a longer 24-month open-label Phase 2 study. *Id.* ¶ 3.

Beginning in August 2021, Cassava became embroiled in public controversy concerning alleged research misconduct and data manipulation related to its pre-clinical and clinical work on simufilam. *Id.* ¶¶ 4–5. Specifically, a Citizen Petition filed with the FDA challenged the integrity of pre-clinical publications about simufilam's mechanism of action and questioned the Phase 2b results. *Id.* ¶¶ 5, 67–69. Following the Citizen Petition, the SEC, DOJ, and CUNY began investigating the allegations. *Id.* ¶¶ 73–76, 79–81.

While these investigations ran their course, Cassava moved forward with planning and executing two Phase 3 trials—RETHINK-ALZ and REFOCUS-ALZ—which were designed to test the safety and efficacy of simufilam in more than 1,900 patients with mild-to-moderate Alzheimer's disease. *Id.* ¶¶ 92–98. The trials tested the effect of 50-mg and 100-mg doses of simufilam versus a placebo over 52- and 76-week periods. *Id.* The trials occurred at clinical sites

[2] By repeating Plaintiffs' allegations from the Amended Complaint, Defendants do not adopt those allegations or in any way concede their truth.

in the U.S., Canada, Australia, Puerto Rico, and South Korea. *Id.* Between April and September 2022, before beginning the trials, Cassava audited and inspected Dr. Wang's CUNY laboratory and concluded that the lab was "temporarily not qualified" for future Cassava work. *Id.* ¶ 78.[3]

On October 12, 2023, *Science* magazine published a leaked, approximately 50-page draft document that purported to report results of CUNY's internal inquiry into allegations of research misconduct by Dr. Wang (the "CUNY Report"). *Id.* ¶ 79. The report said that the committee was "unable to objectively assess the merits of the allegations" because Dr. Wang failed to produce underlying data and records and because the available published images were of low quality. *Id.*[4]

The same day, Cassava issued a statement explaining that: (1) CUNY did not interview any Cassava employees; (2) the CUNY Report made "no findings of data manipulation" and only definitively found issues with Dr. Wang's internal recordkeeping; and (3) doubts existed about the authenticity of the report. *Id.* ¶¶ 80, 123. Later that month, CUNY stated it would not comment on the accuracy of the investigation referenced in the media because no final action had been taken. *Id.* ¶ 81. CUNY also recognized questions about the "confidentiality and integrity" of the process and thus stayed the underlying investigation pending a comprehensive review. *Id.*

By November 2023, Cassava had completed its 24-month open-label Phase 2 study, and its Phase 3 trials had been fully enrolled. *Id.* ¶¶ 63, 98, 112–115. On February 7, 2024, Cassava announced top-line results from the open-label study. *Id.* ¶ 159. The Company stated that 47 mild

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[3] The Court can find this audit report attached to this Motion as Exhibit A. The Court may consider documents attached to a motion to dismiss if the documents are "sufficiently referenced in the complaint." *Walch v. Adjutant Gen.'s Dep't of Texas*, 533 F.3d 289, 294 (5th Cir. 2008).

[4] The CUNY Report is only available for download through the October 12, 2023, *Science* article referenced above. However, the document is password-protected and cannot be filed with the Court using the ECF filing system. The document can be found at the following URL: https://www.science.org/do/10.1126/science.adl3444/full/cuny_wang_final_report-1698701360173.pdf. *See Walch*, 533 F.3d at 294.

Alzheimer's patients receiving continuous simufilam for 24 months had no decline in ADAS-Cog (a measure of cognition) as a group, while 40 non-continuous mild patients declined only 1 point as a group. *Id.* ¶¶ 99, 160. For moderate Alzheimer's, 32 continuously treated patients declined 11.05 points on ADAS-Cog as a group. *Id.* ¶¶ 159–163.[5] Cassava repeated this summary in its 2023 Annual Report and Q1–Q3 2024 Forms 10-Q. *Id.* ¶¶ 162–164.

In late February 2024, Cassava disclosed that an internal investigation conducted by outside counsel had "found no evidence to substantiate allegations that the Company or its employees engaged in or were aware of research misconduct." *Id.* ¶¶ 129–30. The Company also stated then (as well as on multiple other occasions between November 2023 and May 2024) that no government agency had informed Cassava that it found evidence of research misconduct or wrongdoing by the Company or its officers, employees, or directors. *Id.* ¶¶ 125, 127.

In the summer of 2024, the status of the government's investigations changed. On June 28, 2024, DOJ indicted Dr. Wang for allegedly manipulating western blot images in pre-clinical research submitted to the National Institutes of Health (NIH). *Id.* ¶¶ 86, 137. DOJ did not bring any charges against Cassava or any of the Company's current or former employees. On October 23, 2025, DOJ voluntarily dismissed the case against Dr. Wang with prejudice after a jury had been chosen.[6]

On July 1, 2024, Cassava filed an 8-K disclosing that the SEC had told the Company that Dr. Wang could theoretically have used statistics in a May 14, 2020 email attachment sent from

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[5] The Court can find the February 7, 2024 press release announcing these results attached to this Motion as Exhibit B. *See id.*

[6] The Court can find the order of dismissal attached to this Motion as Exhibit C. *See Norris v. Hearst Tr.*, 500 F.3d 454, 461 n.9 (5th Cir. 2007) ("it is clearly proper in deciding a 12(b)(6) motion to take judicial notice of matters of public record.").

Dr. Burns to Dr. Wang to unblind himself as to some Phase 2b participants. *Id.* ¶¶ 141, 148. On July 17, 2024, Mr. Barbier and Dr. Burns resigned from Cassava "other than for cause," and Rick Barry was appointed Executive Chairman and principal executive officer (later CEO). *Id.* ¶¶ 144–147. On August 8, 2024, Cassava cautioned investors not to place undue reliance on the CUNY CSF (cerebrospinal fluid) bioanalysis underlying the Phase 2b results and disclosed that it was in "advanced" settlement discussions with the SEC. *Id.* ¶¶ 149, 151.

On September 26, 2024, the SEC filed a civil complaint against Cassava, Mr. Barbier, and Dr. Burns concerning statements about the 2020 Phase 2b results, and Cassava announced that it had settled with SEC. *Id.* ¶¶ 153–55. Cassava, without admitting or denying the SEC's allegations, agreed to pay a monetary penalty of $40 million. *Id.* The SEC's charges included only negligent disclosure failures. It did not bring any fraud charges against Cassava, Mr. Barbier, or Dr. Burns or otherwise allege that Cassava or any current or former Cassava employees committed fraud. And while the SEC separately charged Dr. Wang with manipulating or fabricating simufilam's Phase 2b research results, *see id.* ¶ 156, the SEC did not allege that Cassava, Mr. Barbier, or Dr. Burns had intentionally or knowingly aided Dr. Wang in doing so.[7]

On November 25, 2024, Cassava announced that RETHINK-ALZ failed to meet its clinical endpoints. *Id.* ¶ 178. Cassava discontinued REFOCUS-ALZ and the Phase 3 open-label extension. *Id.* ¶ 119. On March 25, 2025, top-line data showed REFOCUS-ALZ likewise failed to meet its endpoints. *Id.* ¶ 186. Cassava therefore announced it would discontinue efforts to develop simufilam for Alzheimer's disease. *Id.* ¶¶ 187–190.

B. Procedural Background

1. *The Consolidated Action*

[7] The Court can find the SEC Complaint attached to this Motion as Exhibit D. *See Norris*, 500 F.3d at 461 n.9; *Walch*, 533 F.3d at 294.

In August 2021, after the Citizen Petition was made public, several putative securities class actions were filed in this District against Cassava and certain officers. On June 30, 2022, this Court consolidated those actions as *In re Cassava Sciences, Inc. Securities Litigation*, appointed a lead plaintiff, and approved lead counsel. *See* Consolidated Action, Dkt. 59. The same counsel representing Plaintiffs in the instant action, Pomerantz LLP, filed a motion for appointment as lead plaintiff and approval of counsel, which this Court denied. *See id.*, Dkt. 38, 59. The lead plaintiff in the Consolidated Action filed an operative pleading in August 2022 defining a class period of September 14, 2020, to July 26, 2022. *See id.,* Dkt. 68, ¶ 46. The consolidation order in the Consolidated Action provides that "any other actions now pending or hereafter filed in this District that *arise out of the same facts and claims* as alleged in the [consolidated] actions *shall be consolidated* into the Consolidated Action for all purposes once the Court is informed of them." *See id.*, Dkt. 58, ¶ 5 (emphasis added).

After failing to secure lead counsel status in the Consolidated Action, Pomerantz LLP tried another approach. In February 2024, the firm filed a separate, overlapping case in the Northern District of Illinois—*Baker v. Cassava Sciences, Inc.*, No. 1:24-cv-977 (the "Baker Action"), which began its class period the day after the end of the class period in the then-operative complaint in the Consolidated Action. *See* Baker Action, Dkt. 1. The Consolidated Action plaintiffs moved to transfer and consolidate the Baker Action, explaining that it was a continuation of the same scheme they had already alleged. *See id.*, Dkt. 12. On May 28, 2024, the Baker Action was transferred to the Western District of Texas, *see id.*, Dkt. 42. This Court then consolidated *Baker* pursuant to the June 2022 order. *See* No. 1:24-cv-590-DAE, Dkt. 73. Thereafter, the plaintiffs in the Consolidated Action obtained leave to supplement their complaint and added several 2024 developments, including the June 2024 indictment of Dr. Hoau-Yan Wang, the July 2024 leadership changes, and

the September 2024 SEC resolution. *See* Consolidated Action, Dkts. 175, 176. And on May 22, 2025, lead plaintiffs filed a Second Supplemented Consolidated Complaint, now the operative pleading in the Consolidated Action. *See id.*, Dkt. 319.

The operative complaint in the Consolidated Action broadly alleges that between September 14, 2020, and October 12, 2023, Cassava Sciences and several executives, including Mr. Barbier, Dr. Burns, and Mr. Schoen, misled investors about the scientific validity of simufilam. *See id.* ¶¶ 1–3, 46, 69–72, 287. The complaint asserts that Cassava's foundational pre-clinical and clinical studies were manipulated and contained falsified data produced by Dr. Wang and Dr. Burns. *See id.* ¶¶ 146–148, 216, 287. The complaint further alleges that, following the 2021 Citizen Petition, Cassava falsely denied wrongdoing, issued public statements that were allegedly knowingly false about the status of government investigations, and submitted doctored images to journals to obtain exculpatory notices. *See id.* ¶¶ 319–321, 331–336, 338–345, 363–367, 386–391, 451–453. The complaint concludes that Defendants' manipulation of data and concealment of their wrongdoing was revealed by, among other things, the leak of the October 2023 CUNY Report; the June 28, 2024 DOJ indictment of Dr. Wang for major fraud; the Company's 8-K filings and press releases in July and August of 2024; and the September 26, 2024 SEC charges against Cassava, Mr. Barbier, and Dr. Burns. *See id.* ¶¶ 1–5, 506.

2. *The Instant Action*

Filed in December 2024, the original complaint (then captioned *Crocker v. Cassava Sciences, Inc.)* focused narrowly on Cassava's Phase 3 clinical trial results and proposed a February 7 to November 24, 2024 class period. *See* Dkt. 1. After the lead-plaintiff process concluded, newly appointed lead plaintiffs—represented again by Pomerantz LLP—filed the operative Amended Complaint in August, *see* Dkt. 49, abandoning the original, narrow focus on Phase 3. Like the Baker Action before it, the Amended Complaint copied the same multi-year

scheme alleged in the Consolidated Action and proposed a class period that runs from the day after the end of the Consolidated Action's current class period (October 13, 2023) through March 25, 2025. The Amended Complaint also added individual defendants from the Consolidated Action: Remi Barbier, Eric Schoen, and Dr. Lindsay Burns.

Adopting the narrative in the Consolidated Action, Pomerantz's Plaintiffs now allege that Cassava and certain current and former executives continued to mislead investors through an ongoing cover-up of the same supposed fraud alleged in the Consolidated Complaint. Specifically, Plaintiffs allege that Defendants falsely: (1) misrepresented the outcome and status of government, internal, and third-party investigations, *see* Am. Compl. ¶¶ 123–125, 127–133, 140–141, 143; (2) continued to reference the results of the Phase 2b study, *see id.* ¶¶ 134–136; (3) reported the Phase 2 open-label results and characterized the results as promising for simufilam's potential efficacy, *see id.* ¶¶ 99–101, 115, 159–165, 168, 171–175, 177; and (4) failed to connect the departures of Dr. Burns and Mr. Barbier from Cassava to misconduct alleged in ongoing government investigations, *see id.* ¶¶ 144–148. Plaintiffs broadly claim that the falsity of these challenged statements were revealed by Dr. Wang's indictment; Cassava's July 1 and August 8, 2024 Form 8-Ks; the September 26, 2024 SEC settlement; and the November 25, 2024 and March 25, 2025 Phase 3 trial results, all described above. *See, e.g.*, *id.* ¶¶ 243–44, 248, 250.

LEGAL STANDARD

To survive a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), a complaint must contain sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim has facial plausibility when the pleaded factual content allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. *Id.* Although the court must accept all well-pleaded factual allegations as true and view them in the

light most favorable to the plaintiff, it is not bound to accept as true legal conclusions couched as factual allegations. *Twombly*, 550 U.S. at 555; *In re Katrina Canal Breaches Litig.*, 495 F.3d 191, 205 (5th Cir. 2007). Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice. *Iqbal*, 556 U.S. at 678.

The PSLRA imposes a separate, heightened pleading requirement in federal securities class actions, which requires that the plaintiff specify each alleged misleading statement, explain why it was misleading, and allege particularized facts giving rise to a strong inference of scienter. *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 321 (2007); *Abrams v. Baker Hughes Inc.*, 292 F.3d 424, 430–31 (5th Cir. 2002). Rule 9(b) additionally requires that fraud claims be pled with particularity, a standard the Fifth Circuit interprets strictly. *Tuchman v. DSC Commc'ns Corp.*, 14 F.3d 1061, 1067 (5th Cir. 1994). This standard requires a plaintiff to specify the "who, what, when, where, and how" of the alleged fraud. *Dorsey v. Portfolio Equities, Inc.*, 540 F.3d 333, 339 (5th Cir. 2008). Specifically, the complaint must identify the fraudulent statements, the speaker, the time and place they were made, and explain why the statements were fraudulent. *Williams v. WMX Techs., Inc.*, 112 F.3d 175, 177–78 (5th Cir. 1997).

Therefore, to state a claim under Section 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder, a plaintiff must plead six elements: (1) a material misrepresentation or omission by the defendant; (2) scienter, meaning an intent to deceive, manipulate, or defraud (or at least severe recklessness); (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation, meaning that the misrepresentation proximately caused the plaintiff's alleged injury. *See Tellabs*, 551 U.S. at 319.

ARGUMENT

Plaintiffs' Amended Complaint targets four categories of statements made by Defendants during the Class Period: statements (1) regarding government, internal, and third-party investigations; (2) referencing the historical results of Cassava's Phase 2b study of simufilam; (3) summarizing and characterizing the results of a separate, 24-month Phase 2 open-label study of simufilam; and (4) concerning the departures of Dr. Burns and Mr. Barbier from Cassava. None of the alleged misstatements states a claim.

For each category, Plaintiffs fail to plead particularized facts sufficient to establish the essential elements of a claim under Section 10(b) and Rule 10b-5, particularly when evaluated under the heightened pleading standards of the PSLRA and governing Fifth Circuit precedent. The claims fail because Plaintiffs do not adequately plead (1) any actionable or material misrepresentation or omission, (2) the required strong inference of scienter, or (3) loss causation for any challenged statement. The Amended Complaint must therefore be dismissed.

A. Plaintiffs Fail to Identify Any Actionable or Material Misrepresentation or Omission Made by Defendants

To adequately plead an actionable misrepresentation or omission, Plaintiffs must allege particularized facts demonstrating that the challenged statement was materially false or misleading *when made*. *See Masel v. Villareal*, 924 F.3d 734, 748 (5th Cir. 2019); *Kin-Yup Chun v. Fluor Corp.*, 2021 WL 1788626 (N.D. Tex. May 5, 2021). Mere disagreements over interpretation or corporate puffery do not suffice. *See Southland Sec. Corp. v. INSpire Ins. Solutions, Inc.*, 365 F.3d 353, 371–72 (5th Cir. 2004). Moreover, a statement is only misleading if it would have misled a "reasonable investor" reading it "fairly and in context" including "all [the] surrounding text, including hedges, disclaimers, and apparently conflicting information." *Omnicare Inc. v. Laborers District Council Construction Industry Pension Fund*, 575 U.S. 175, 186-89, 191, 194 (2015). For

alleged omissions, Plaintiffs must show Defendants had a duty to disclose the omitted information. *See R2 Invs. LDC v. Phillips*, 401 F.3d 638, 644–46 (5th Cir. 2005).

1. *Plaintiffs fail to identify any misrepresentation or omission made by Defendants about the government, internal, and third-party investigations.*

The first category of alleged misstatements in the Amended Complaint concerns Defendants' public statements about government, internal, and third-party investigations. Plaintiffs target: (1) an October 12, 2023 press release responding to the CUNY Report, stating it made "no findings of data manipulation" and CUNY had "no legitimate basis" for accusations against Cassava personnel because it "did not interview any employee of Cassava," Am. Compl. ¶ 123; (2) statements in SEC filings (Nov. 7, 2023; Feb. 28, 2024; and May 10, 2024) that "[n]o government agency has informed the Company that it has found evidence of research misconduct or wrongdoing by the Company or its officers, employees or directors," *id.* ¶¶ 125, 127, 132; and (3) a February 28, 2024 press release and Annual Report stating an internal investigation by Orrick found "no evidence to substantiate allegations that the Company or its employees engaged in or were aware of research misconduct," *id.* ¶¶ 129–130.

Plaintiffs fail to plead particularized facts showing that any of these statements were false or misleading. Indeed, Plaintiffs do not allege that: (1) the October 12, 2023 press release mischaracterized the CUNY Report; (2) CUNY had, in fact, interviewed Cassava employees; (3) any government agency had informed Cassava of evidence of research misconduct or wrongdoing by the Company or its personnel at the time the statements were made; or (4) Cassava's internal investigation by Orrick *had* uncovered evidence to substantiate claims that Cassava or its employees engaged in or were aware of research misconduct (it did not). In fact, each challenged statement was true.

First, Cassava's October 12, 2023 statement accurately characterized the CUNY Report, which the report itself confirms. The report states that the CUNY committee was "unable to objectively assess the merit of the allegations" and could not "make an objective assessment for even a single allegation" due to Dr. Wang's failure to provide underlying data. CUNY Report at 1, 7. Thus, CUNY did not make any final, adjudicated findings of misconduct; Cassava merely accurately summarized that status and noted questions about the report's authenticity. Am. Compl. ¶ 80. Further, the report details interviews only with Dr. Wang and CUNY personnel; there is no mention of interviews with Cassava employees. CUNY Report at 1, 3–4. Cassava's conclusion that CUNY therefore had "no legitimate basis" for accusations against Company employees based on that report is, at worst, a non-actionable statement of opinion regarding an admittedly inconclusive third-party document. *See Southland*, 365 F.3d at 371–72 (distinguishing between factual statements and opinions or puffery, explaining that statements are non-actionable when they are "of the vague and optimistic type that cannot support a securities fraud action . . . and contain no concrete factual or material misrepresentation"). Finally, *Science* magazine made the report *publicly available* before Cassava's statement about it through a link in its article about the report. *See supra,* fn. 4. Thus, investors were free to evaluate Cassava's brief characterization against the primary source—the report itself. *See Kapps v. Torch Offshore, Inc.*, 379 F.3d 207, 216 (5th Cir. 2004) (holding that alleged misrepresentations regarding gas prices were not materially misleading, where gas prices are publicly available).

Second, the statements in SEC filings—that "[n]o government agency has informed the Company that it has found evidence of research misconduct or wrongdoing by the Company or its officers, employees or directors," Am. Compl. ¶¶ 125, 127, 132—were factually correct reports of the communications received by the Company *at that time*. Plaintiffs plead no facts suggesting

that any government agency had, in fact, informed Cassava of any such findings before May 10, 2024 (the date of the last challenged statement).

Plaintiffs instead complain the statements were "artfully" worded to omit third parties like Dr. Wang. *See id.* ¶¶ 128, 131. But Defendants' statements were not "artful"; they specifically and clearly referenced what the government had (or had not) told them about Cassava's own officers, employees, and directors. Plaintiffs make no allegation that the government had told Cassava anything about any wrongdoing by Dr. Wang or any other third party. *See Ind. Elec. Workers' Pension Tr. Fund IBEW v. Shaw Grp., Inc.*, 537 F.3d 527, 541 (5th Cir. 2008) (stating that for an omission to be actionable it must "affirmatively create an impression of a state of affairs that differs in a material way from the one that actually exists"); *see also Gambrill v. CS Disco, Inc.*, 2025 WL 388828, at *6 (W.D. Tex. Jan. 30, 2025) (Ezra, J.). Defendants had no duty to disclose more than what they accurately stated regarding information received about the Company and its personnel. *See R2 Invs.*, 401 F.3d at 643–44 (finding no duty to disclose internal analyses or speculate on future outcomes where statements made were accurate). Reporting accurately on what has (and has not) been communicated is not fraud. Plaintiffs' contrary theory would impose a duty the securities laws do not recognize; to opine on the status of non-Company actors in the middle of confidential agency inquiries.

Third, the February 28, 2024 statement that an internal investigation by Orrick found "no evidence to substantiate allegations that the Company or its employees engaged in or were aware of research misconduct," Am. Compl. ¶¶ 129–130, accurately reported the findings of that investigation. Plaintiffs plead no facts suggesting this statement misrepresented Orrick's actual findings or conclusions about the Company and its employees. Again, Plaintiffs complain the statement omits third parties, *id.* ¶ 131, but Plaintiffs have not alleged that Orrick's investigation

found any wrongdoing by such third parties, let alone that the scope of the investigation even included third parties like Dr. Wang. It's not parsing. A company may accurately disclose the results of its internal investigation focused on its own personnel without speculating about the actions of its vendors. *See R2 Invs.*, 401 F.3d at 643–44.

2. *Plaintiffs fail to plead that statements referencing historical Phase 2b results were material misrepresentations.*

Plaintiffs next challenge Defendants' references in a March 2024 presentation by Dr. Burns and Cassava's May 10, 2024 Form 10-Q to the positive results originally reported from the Phase 2b study in 2020. Am. Compl. ¶¶ 132–36. Plaintiffs allege that these summaries were misleading because Defendants knew the data was unreliable. *Id.* ¶¶ 134–136. This claim fails to identify an actionable misrepresentation for several reasons.

First, the statements accurately recounted clinical results that had already been reported years earlier. *Id*. Plaintiffs do not allege these summaries inaccurately described what the Company *had originally claimed*. And accurately summarizing historical results is not misleading. *See Nathenson v. Zonagen Inc.*, 267 F.3d 400, 419–20 (5th Cir. 2001); *see also Kapps*, 379 F.3d at 211–12; *McCloskey v. Match Grp., Inc.*, 2018 WL 4053362, at *4 (N.D. Tex. Aug. 24, 2018) ("Courts have consistently rejected attempts by plaintiffs to plead falsity based on accurate reports of historical performance.").

Second, information already disseminated cannot form the basis of a fraud claim. *See Kapps*, 379 F.3d at 213–14 & n.7 (emphasizing the importance of the "total mix" of information available to the market). By early 2024, the market was saturated with information challenging the Phase 2b study. For example, an August 2021 Citizen Petition (and three supplements) called the Phase 2b results into question and raised concerns about Dr. Wang's performing the Phase 2b re-analysis. Contemporaneous press reports suggested that the SEC and DOJ were investigating

Cassava based on these same concerns. *See* Am. Compl. ¶¶ 66–69, 74–76. Indeed, these precise allegations formed the basis of a number of claims in the Consolidated Action. *See* Consolidated Action, Dkt. 68. Given this extensive public discourse, brief, accurate summaries of the results originally reported nearly four years prior were not misleading; reasonable investors could evaluate them in light of the known controversies. *See Greenberg v. Crossroads Sys., Inc.*, 364 F.3d 657, 670–72 (5th Cir. 2004); *Kapps,* 379 F.3d at 213–14 n.7.

3. *Plaintiffs fail to identify any misrepresentations Defendants made about the Phase 2 open-label results.*

Plaintiffs next challenge statements made between February 7, 2024, and October 8, 2024—including descriptions in press releases, SEC filings (such as the 2023 Form 10-K and subsequent Form 10-Qs), open letters, and executive commentary—characterizing results from the 24-month Phase 2 open-label study. Plaintiffs target statements about "No Decline in Cognition Scores" for certain patients completing the study, Am. Compl. ¶¶ 159, 163–164, and optimistic descriptions of those results like "stable cognition," "unlike any Alzheimer's trial ever," "remarkable," and "unheard of," *id*. ¶¶ 168, 171, 173, 175. Plaintiffs allege these were misleading primarily because they omitted details about the methodology of the study and were overly positive. *Id.* ¶¶ 29, 102–114, 165. These statements are not actionable for several reasons.

First, the core factual statements that Defendants made about the Phase 2 open-label results were accurate. Specifically, (1) "[p]atients with mild Alzheimer's disease who received simufilam treatment continuously for two years" in fact "had no decline in ADAS-Cog scores" as a group; (2) "[p]atients with mild Alzheimer's who received simufilam treatment non-continuously" in fact "declined 1 point on ADAS-Cog" as a group; and (3) "[p]atients with moderate Alzheimer's who received simufilam treatment continuously for two years" in fact "declined 11.05 points on ADAS-Cog" as a group. *See Id.* ¶ 160. Plaintiffs do not allege that any of these statements were false.

Reporting factually accurate results for clearly defined statistical subgroups is not fraudulent. *See Nathenson*, 267 F.3d at 420.

Second, Defendants accurately disclosed the relevant analysis sets and methodology. Plaintiffs claim that Defendants hid the study's methodology by failing to reveal that the accurate results (described above) were recorded from only a subset of the over 200 patients who initially entered the study. Am. Compl. ¶¶ 102–109, 165. This is incorrect. The February 7, 2024 press release that first disclosed the results explicitly stated that the "study enrolled *over 200 patients with mild to moderate Alzheimer's*" and that the results applied to cohorts of "n=47," "n=40," and "n=32" respectively, clearly identifying that those results were derived from a subset of the original 200 participants. *See* Ex. B [February 7 Press Release] (emphasis added).

Plaintiffs cite ICH E9 as the analysis set standard they would have preferred, but they do not allege the Defendants claimed ICH compliance for the Phase 2 open-label study or that using a different end-of-trial analysis set rendered any statement about the open-label results false. Plaintiffs' preference for a different analysis set is a non-actionable disagreement over methodology. *See Nathenson*, 267 F.3d at 419–20 ("where a company accurately reports the results of a scientific study, it is under no obligation to second-guess the methodology of that study").

Third, Plaintiffs are incorrect that Cassava did not warn investors that the analysis set used in the Phase 2 open-label study may differ from the analysis set used in the later, Phase 3 study. Am. Compl. ¶ 110. Indeed, Cassava's 2023 annual report stated that because "FAS data is specific to each phase of a study, the FAS for the 24-month study *may differ from the FAS for other phases*." *See id.* ¶ 163.

Fourth, the February 7, 2024 press release's "Study Limitations" section squarely disclosed the limitations of the open-label study that Plaintiffs claim were concealed by Defendants: that

open-label design and small subgroups "may introduce clinical or statistical bias"; that "different methods of statistical analysis . . . may lead to objectively different numerical results"; that results were "top-line" and subject to change pending a final audit; and that open-label data "do not constitute . . . regulatory evidence of safety or efficacy." *See* February 7 Press Release. These disclosures defeat any omission theory and reinforce that any characterizations of the study's results were framed with the study's limitations. *See Omnicare*, 575 U.S. at 189–94 (opinion statements not actionable where basis and uncertainty are disclosed); *see also Rubinstein v. Collins*, 20 F.3d 160, 167–68 (5th Cir. 1994).

Fifth, optimistic descriptors like "remarkable," "unheard of," or "unlike any Alzheimer's trial ever" constitute non-actionable corporate puffery when applied to accurately reported data from an early-stage, open-label study. That is especially so when the same disclosures caution about bias, method sensitivity, and provisional "top-line" status. *See* Am. Compl. ¶ 175 (Mr. Barry's October 8, 2024 letter about the Phase 2 open-label results notes that the study "was not powered for, and did not reach, statistical significance" and recommends readers "review the results for yourself."). These are "generalized, optimistic statement[s]" lacking measurable specificity upon which no reasonable investor would rely as guarantees. *See Rosenzweig v. Azurix Corp.*, 332 F.3d 854, 869 (5th Cir. 2003); *Southland*, 365 F.3d at 372.

Finally, Defendants had no duty to speculatively compare the Phase 2 results' predictive value to potential Phase 3 outcomes when reporting the Phase 2 data. Companies are not required to preface accurate reports of current data with speculative analyses of future trial designs. *See R2 Invs.*, 401 F.3d at 643–44. The inherent differences and risks between study phases are well understood, *see, e.g., Nathenson,* 267 F.3d at 404 (acknowledging the well-understood differences

between clinical trial phases), and were, in any event, disclosed by Defendants along with the Phase 2 open-label results, *see supra*.

4. *Plaintiffs fail to plead that statements about executive departures from Cassava were false or misleading.*

Lastly, Plaintiffs challenge statements in the July 17, 2024 Form 8-K concerning the departures of Barbier and Burns, alleging they misleadingly omitted the connection to the ongoing investigations. *See* Am. Compl. ¶¶ 145, 147–148. This claim fails because the statements were true, and Defendants had no duty to disclose internal reasons for the changes at that time.

The statements about Barbier's resignation—describing it as "Other Than for Cause" and "not a result of any disagreement with the Company on any matter relating to the Company's operations, policies or practices"—accurately reflected the contractual characterization and the standard disclosure language used to comply with Item 5.02(a)(2) of Form 8-K. *Id*. ¶ 145. Plaintiffs plead no facts showing these characterizations were untrue under Barbier's agreement or that a reportable disagreement occurred. Nor did the securities laws require Defendants to disclose internal reasons for the personnel changes; companies must only disclose the fact of an executive departure unless plaintiffs have "alleged facts that demonstrate that defendants had a duty provide more detail on the reason for [the executive's] departure." *See Firefighters Pension & Relief Fund of the City of New Orleans v. Bulmahn*, 147 F. Supp. 3d 493 (E.D. La. 2015), *aff'd sub nom. Neiman v. Bulmahn*, 854 F.3d 741 (5th Cir. 2017). And Plaintiffs have alleged no such facts here.

As for the accompanying aspirational statements by the new Chairman on the Company's commitment to "transparency, accountability, and highest ethical business practices," Am. Compl. ¶ 147, Plaintiffs have pleaded no facts that render those statements false. Further, those are another example of non-actionable corporate puffery lacking the measurable specificity required to be actionable. *See Rosenzweig*, 332 F.3d at 869; *Southland*, 365 F.3d at 372.

B. Plaintiffs Fail to Allege a Strong Inference That Defendants Acted with an Intent to Deceive or Severe Recklessness

Even if Plaintiffs could identify an actionable misstatement, their claims would fail for lack of scienter. To plead scienter, Plaintiffs must allege particularized facts giving rise to a "strong inference" that Defendants acted with intent to deceive or with "severe recklessness." *Flaherty & Crumrine Preferred Income Fund, Inc. v. TXU Corp.*, 565 F.3d 200, 207 (5th Cir. 2009). Severe recklessness involves "highly unreasonable omissions or misrepresentations" reflecting "an extreme departure from the standards of ordinary care." *Id.* (internal citation omitted). Crucially, the inference of scienter must be "cogent and compelling," not merely "reasonable," and must be "at least as compelling as any opposing inference one could draw from the facts alleged." *Tellabs*, 551 U.S. at 324. Allegations of motive and opportunity, without more, are insufficient to satisfy this standard. *See Rosenzweig*, 332 F.3d at 867 ("It is well established that bare allegations of motive and opportunity will not suffice to demonstrate scienter").

Plaintiffs first attempt to establish scienter by asking the Court to infer that Defendants knew that Dr. Wang had manipulated the Phase 2b study data (and therefore knew that their statements about that data and related investigations were misleading) based on two pieces of information: (1) Cassava's internal vendor audit of Dr. Wang's lab conducted in between April and September 2022, and (2) the email sent by Dr. Burns to Dr. Wang in May 2020. Neither supports the necessary inference.

First, the audit of Dr. Wang's laboratory at CUNY was a routine "Vendor Qualification" review, focused on determining Dr. Wang's suitability for *future* work; it was *not* an investigation of allegations of past misconduct against Dr. Wang. *See* Ex. A [Audit Rep.] at 5. And while the audit found procedural and quality-control issues (*e.g.*, "lack of experiment logbooks," deficient "sample management," and uncalibrated equipment), which resulted in a finding that the lab was

"unacceptable and temporarily not qualified" for *future studies*, it did *not* conclude that Dr. Wang had fabricated or falsified data *in the past*. *See id.* at 4–5, 7. Poor recordkeeping or quality control issues in 2022 do not equate to data falsification in 2020, nor do such findings render the specific statements Plaintiffs' challenge—made over a year later about entirely separate topics (*i.e.*, the CUNY draft report, government communications, and internal investigation findings about employees)—false. The audit is too remote in time and distinct in subject matter to carry the probative weight Plaintiffs demand of it.

Second, the existence of the May 2020 email and attachment from Dr. Burns to Dr. Wang does not support an inference of falsity regarding the challenged statements. While Plaintiffs allege that the email attachment contained statistical information that could have allowed Dr. Wang to partially unblind himself, Am. Compl. ¶¶ 13, 128, they crucially fail to plead any facts that plausibly establish that Defendants *knew* about this theoretical possibility *at the time* the challenged statements were made between October 2023 and May 2024. Indeed, Defendants concededly did not understand any theoretical unblinding implications *until after* the challenged statements were made. Cassava's July 1, 2024 8-K disclosure—a document upon which Plaintiffs explicitly rely—revealed that the Company learned of this possibility only when the SEC "*recently* provided the Company with new information obtained during its investigation," *i.e.*, in mid-2024. *Id.* ¶ 140 (emphasis added). Only then did Cassava determine the email attachment "could have been used" for partial unblinding. *Id.*

The securities laws do not recognize "fraud by hindsight." That is, statements cannot be retroactively rendered fraudulent by discoveries made years later unless failure to make such discoveries prior to those statements was "severe[ly] reckless[]." *Flaherty*, 565 F.3d at 207. Severe recklessness is "only present in situations where there is a danger of misleading buyers or sellers

which is either known to the defendant or is *so obvious* that the defendant must have been aware of it." *Local 731 I.B. of T. Excavators & Pavers Pension Tr. Fund v. Diodes, Inc.*, 810 F.3d 951, 957 (5th Cir. 2016) (emphasis added). Here, any argument that Defendants were severely reckless for failing to understand sooner that Dr. Wang could have partially unblinded himself during the Phase 2b study fails because that discovery was *not at all obvious*. Indeed, Dr. Burns sent the email attachment to Dr. Wang, which contained complex statistical summaries of CSF biomarker data, so that Dr. Wang could evaluate the work of a separate laboratory. *See* Ex. D [SEC Compl.] ¶¶ 37–41. The SEC only determined that those statistical summaries could be reverse engineered by Dr. Wang to partially unblind himself by undertaking a sophisticated post-hoc analysis, which the agency subsequently explained to Defendants. Plaintiffs do not allege Defendants performed or should have performed a similar analysis prior to making the challenged statements. Thus, Defendants' mere possession of the email and attachment—the significance of which was not yet known and required sophisticated, hindsight analysis to uncover—cannot support an inference of severe recklessness regarding accurate statements made years later about the status of government investigations. *See Lormand v. US Unwired, Inc.,* 565 F.3d 228, 254 (5th Cir. 2009) ("fraud by hindsight" is where "there is no contemporaneous evidence at all that defendants knew earlier what they chose not to disclose until later").

Notably, the SEC itself alleged only *negligence*—not intentional fraud—regarding the email communication. SEC Compl. ¶¶ 88, 105–107. While the SEC alleged that Dr. Wang manipulated the Phase 2b results by partially unblinding himself, the SEC *did not* allege that Dr. Burns intentionally provided him with the statistics in the email attachment *so that he could do so*. *See id.* ¶ 2 ("Dr. Burns *negligently* provided information sufficient to allow Dr. Wang to partially unblind himself.") (emphasis added). If it was evident that the email attachment could be reverse

engineered by Dr. Wang to manipulate the Phase 2b data, then SEC would not have concluded that Dr. Burns was merely *negligent* in providing that attachment to Dr. Wang.

Thus, Plaintiffs fail entirely to plead particularized facts showing Defendants knew or even suspected that Dr. Wang had, in fact, manipulated the Phase 2b data or even that Defendants understood that Dr. Wang could be partially unblinded during the Phase 2b study when the statements they challenge were made. *See Shaw Grp.*, 537 F.3d at 542–43 (rejecting inference of knowledge based on access to internal data and allegations that defendants "must have known" without specific facts showing contemporaneous awareness of the falsity). Cassava's July 1, 2024 Form 8-K disclosed that Dr. Wang may have been partially unblinded and subsequent explicit warning in August 2024 *not* to rely on the Phase 2b data are not indicative of fraud or prior concealment, but rather of the Company's evolving understanding and honest attempt to update investors with material information as the Company learned of it.

Plaintiffs also fail to plead scienter regarding Defendants' statements about the Phase 2 open-label study. Accurately reporting results for a specific study group using a disclosed FAS methodology, while contemporaneously warning of study limitations and provisional "top-line" status, does not imply fraudulent intent or severe recklessness. And boilerplate allegations that executives had access to data and an obligation to ensure accuracy are insufficient under the PSLRA to plead scienter, especially when the reported clinical trial results were accurate as reported. *See Nathenson*, 267 F.3d at 420.

Finally, Plaintiffs' attempt to establish scienter with generalized allegations of motive, Am. Compl. ¶¶ 220–227, and opportunity, *id.* ¶¶ 228–234, fails under Fifth Circuit law. A universal desire to raise capital does not establish scienter. *See Owens v. Jastrow*, 789 F.3d 529, 539 (5th Cir. 2015). And such generalized allegations do not automatically impute knowledge of falsity

without particularized facts linking defendants to contemporaneous knowledge contradicting those statements, which Plaintiffs have not alleged. *See In re ArthoCare Corp. Sec. Litig.*, 726 F. Supp. 2d 696, 719–20 (W.D. Tex. 2010).

In sum, Plaintiffs offer no particularized facts suggesting Defendants intended to deceive investors or were severely reckless when making accurate statements about ongoing and evolving investigations, Phase 2 open-label study results, or executive departures from Cassava. The opposing inference—that Defendants accurately reported information based on contemporaneous understanding while navigating complex and confidential inquiries—is far more plausible than Plaintiffs' theory of deliberate deception through carefully worded, factually accurate updates.

C. Plaintiffs Fail to Plead That Any of Defendants' Statements Caused Investor Losses

To plead loss causation, Plaintiffs must allege facts plausibly showing a direct causal link between the alleged misrepresentation and their economic loss. *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 342 (2005). This requires explaining with particularity that the stock price declined when the market learned the "relevant truth" previously concealed, typically through a corrective disclosure revealing the falsity of the specific prior statement, and not for other reasons unrelated to the alleged fraud. *See Pub. Emps.' Ret. Sys. of Miss. v. Amedisys, Inc.*, 769 F.3d 313, 320–21 (5th Cir. 2014); *Lormand*, 565 F.3d at 258. Stock declines caused by unrelated news or the materialization of known risks do not establish loss causation. *See Ludlow v. BP, P.L.C.*, 800 F.3d 674, 682 (5th Cir. 2015) (stock drops tied to new adverse events do not necessarily reveal prior falsity). Plaintiffs' attempts to establish loss causation fail, as each of the "corrective" disclosures they allege did not reveal any truth Defendants allegedly concealed.

For example, Plaintiffs allege that the disclosures between June and September 2024—regarding Dr. Wang's indictment, Cassava's discovery of the potential unblinding email, the Company's warning not to rely on Phase 2b data, and the SEC settlement— were "corrective."

Am. Compl. ¶¶ 139, 142, 152, 157. But each of these disclosures revealed *new* information and developments regarding the progression and outcomes of government investigations, not that Defendants' prior status updates about government investigations were false *when made*. That is, they did not reveal any falsity in Defendants' *prior, specific, and true statements* about what the CUNY Report *actually found*, what government agencies *had told* Cassava as of early 2024, or what Orrick *had concluded* as of February 2024. Nor did they correct or even speak to the reasons for Mr. Barbier's or Dr. Burns's departures from Cassava. *See FindWhat Inv'r Grp. v. FindWhat.com*, 658 F.3d 1282, 1311 n.27 (11th Cir. 2011) (cited approvingly in *Amedisys*, 769 F.3d at 321) (corrective disclosure must reveal the falsity of the specific prior statement); *Dura*, 544 U.S. at 342–47 (loss causation requires that the revelation of the truth of the alleged misrepresentation cause the loss); *Alaska Elec. Pension Fund v. Flowserve Corp.*, 572 F.3d 221, 228–31 (5th Cir. 2009) (corrective disclosure must reveal the previously concealed truth).

Plaintiffs alleged corrective disclosures about the Phase 3 trials in November 2024 and March 2025 are similarly flawed. Am. Compl. ¶¶ 178–191. The Phase 3 trials' failure to demonstrate the efficacy of simufilam to treat Alzheimer's was completely disconnected from the alleged falsity of earlier statements about the separate Phase 2 open-label study. Indeed, the failure of a drug in pivotal Phase 3 trials is the materialization of an inherent, disclosed risk in drug development[8] and was the direct cause of the stock collapse. It does not reveal that earlier statements about Phase 2 open-label results, which accurately described different data using a different methodology and expressly cautioned that open-label results are not regulatory evidence

[8] Indeed, Cassava continuously disclosed the risk that the trials may not succeed in demonstrating simufilam's efficacy in SEC filings (such as 10-K filings) throughout simufilam's development.

and may not predict Phase 3 outcomes, were false when made. It simply demonstrates that promising early-stage results did not translate to Phase 3 success, which is a common occurrence.[9]

Thus, Plaintiffs rely on alleged corrective disclosures that did not (and could not) correct any information in the statements by Defendants that they challenge. Their theory of loss causation fails as a matter of law, and their Amended Complaint therefore must be dismissed.

CONCLUSION

Because Plaintiffs have failed, for each category of challenged statements, to plead particularized facts establishing actionable misstatements or omissions, a strong inference of scienter, or loss causation under the heightened standards of the PSLRA and governing Fifth Circuit precedent, the Amended Complaint fails to state a claim upon which relief can be granted and must be dismissed with prejudice unless consolidated into the Consolidated Action.

[9] Additionally, the market reacted positively to the February 2025 ClinicalTrials.gov posting, which revealed the full details regarding the FAS that Plaintiffs claim were fraudulently omitted from the initial disclosures of the Phase 2 open-label results. This further undermines loss causation. If the revelation of the "truth" (the specific FAS definition) caused the stock price to increase, it demonstrates that the allegedly omitted information did not cause Plaintiffs' losses.

Dated: November 6, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned certifies that on November 6, 2025, a true and correct copy of the foregoing was served upon each attorney of record through the Court's CM/ECF system.

/s/ *Gregg Costa*
Gregg Costa